

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

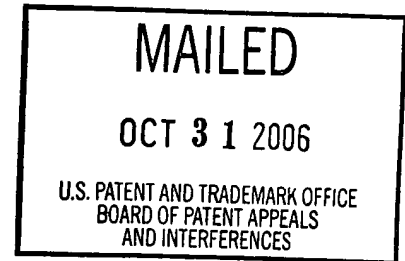
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte FRANK AUSTRUP and
MICHAEL GIESING

Appeal No. 2006-2568
Application No. 09/744,866

ON BRIEF



Before ADAMS, GRIMES, and LINCK, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to methods for isolating disseminated tumor cells. The examiner has rejected the claims as not being supported by an adequate written description. We have jurisdiction under 35 U.S.C. § 134. We reverse.

Background

"Disseminated tumor cells" are "cells which have detached from the primary tumor and circulate in body fluids." Page 6, line 38, to page 7, line 1. The specification states that disseminated tumor cells "are not considered as actual tumor in the medical sense, but [that] they represent cancer cells," as the term is used in the specification. Page 7, lines 1-3.

The specification describes a method for isolating cancer cells from a cell-containing body fluid by passing the fluid through a screen that retains cancer cells. Page 6, lines 11-15. The method "may be applied to all those cell-containing body fluids which have cancer cells," such as bone marrow and blood. Page 12, lines 24-39. The specification states that screens having a mesh width or pore width in a range of 15 μm to 30 μm are preferred. Page 8, line 37, to page 9, line 2.

The specification states that "body fluids may be directly fed to the screening process. However, frequently it is advantageous to subject the cell-containing body fluid to a preliminary work-up first. It is possible, for example, to separate cellular from non-cellular components." Page 13, lines 4-9. "In order to be able to be fed to the screening process, the cell-containing fractions (isolates) isolated beforehand from a body fluid should be present in the form of suspensions." Page 13, lines 34-37.

In addition, the specification states that "it is also possible to modify the cancer cells in the cell suspension prior to the screening process, for example by labeling, by attaching particles, by triggering aggregation and/or cluster formation using, for example, suitable antibodies, enzymes, lectins, other ligands and/or receptors or crosslinking reagents, by fixing and by inducing other defined states." Page 13, lines 25-32.

Discussion

1. Claim construction

Claims 24 and 28 are pending and on appeal. Claims 24 and 28 read as follows:

24. A method for isolating disseminated tumor cells from a cell-containing body fluid, consisting essentially of passing a cell-containing body fluid or part thereof that comprises a disseminated

tumor cell through a screen having a mesh or pore width of about 15 to 30 μm to separate non-cancer cells from disseminated tumor cells, wherein the disseminated tumor cells are retained on the screen wherein the body fluid is selected from the group consisting of blood and bone marrow, wherein the disseminated tumor cells are not modified prior to screening by labeling, by attaching particles, by triggering aggregation, by triggering cluster formation, with antibodies, enzymes, lectins, other ligands, other receptors or cross linking agents or by fixing.

28. A method for isolating disseminated tumor cells from a cell-containing body fluid, consisting essentially of separating cellular components from non-cellular components in a body fluid that comprises a disseminated tumor cell to obtain a cell-containing fraction; resuspending the cell-containing fraction in a suspension medium; and passing the resuspended cell-containing fraction through a screen having a mesh or pore width of about 15 to 30 μm to separate non-cancer cells from disseminated tumor cells, wherein the disseminated tumor cells are retained on the screen, and wherein the body fluid is selected from the group consisting of blood and bone marrow, wherein the disseminated tumor cells are not modified prior to screening by labeling, by attaching particles, by triggering aggregation, by triggering cluster formation, with antibodies, enzymes, lectins, other ligands, other receptors or cross linking agents or by fixing.

Thus, claims 24 and 28 are each directed to a method for isolating disseminated tumor cells from blood or bone marrow. The methods of claims 24 and 28 each involve passing a cell-containing composition through a screen having a mesh or pore width of about 15 to 30 μm to separate non-cancer cells from disseminated tumor cells, the disseminated tumor cells being retained on the screen.

Each of claims 24 and 28 also requires that "the disseminated tumor cells are not modified prior to screening by labeling, by attaching particles, by triggering aggregation, by triggering cluster formation, with antibodies, enzymes, lectins, other ligands, other receptors or cross linking agents or by fixing." To construe the claims, we give this

limitation its “broadest reasonable interpretation consistent with the specification.” In re Sneed, 710 F.2d 1544,1548, 218 USPQ 385, 388 (Fed. Cir. 1983) (emphasis added).

On page 13, the specification states that “it is also possible to modify the cancer cells in the cell suspension prior to the screening process, for example by labeling, by attaching particles, by triggering aggregation and/or cluster formation using, for example, suitable antibodies, enzymes, lectins, other ligands and/or receptors or crosslinking reagents, by fixing and by inducing other defined states.” We interpret this to mean that the cancer cells may be modified – using, for example, antibodies, enzymes, lectins, other ligands, other receptors, or crosslinking reagents – by labeling, attaching particles, triggering aggregation, and/or triggering cluster formation. In addition, the cancer cells may be modified by fixing or by inducing other defined states.

We interpret claims 24 and 28 to exclude the limitations discussed on page 13 of the specification. That is, we interpret claims 24 and 28 to require that the tumor cells are not modified – using antibodies, enzymes, lectins, other ligands, other receptors, or crosslinking reagents – by labeling, attaching particles, triggering aggregation, and/or triggering cluster formation and are not modified by fixing.

2. Written Description

The examiner rejected claims 24 and 28 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Specifically, the examiner argued that the specification does not support the recitation in claims 24 and 28 requiring that the disseminated tumor cells are not modified by various means prior to screening.

The examiner argued that the disclosure in the specification at page 13, lines 25-32, “*positively* recites the inclusion of a step comprising modifying the tumor cells before passing a suspension of the cells through a screen,” but that “the mere presence of a positive recitation is not basis for exclusion.” Examiner’s Answer, page 7. In particular, the examiner argued that, unlike the situation in In re Johnson, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977), Appellants’ original disclosure does not include a description of the species Appellants wish to exclude. Examiner’s Answer, pages 8-9.

Appellants argue that the words “it is also possible” compel interpreting the disclosure at page 13, lines 25-32, to mean that Appellants had in their minds the case where the recited modifications are made and the case where the recited modifications are not made. Appeal Brief, pages 4-5. In addition, Appellants argue that Working Example 1, which “shows screening of unmodified disseminated tumor cells,” “makes it clear” that the inventors had the second alternative in mind. Appeal Brief, page 5.

Compliance with the written description requirement is determined by whether the disclosure shows possession to a person of ordinary skill in the art. Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000). We agree with Appellants that the words “it is also possible” in the disclosure at page 13, lines 25-32, demonstrate that Appellants had possession of both the case where the recited modifications are made and the case where the recited modifications are not made. See In re Johnson, 558 F.2d at 1017-1019, 194 USPQ at 195-196, in which the disclosure of a genus, as well as species within that genus, was held sufficient to support a claim to the genus minus the disclosed species. Thus, we

conclude that the description of modifications at page 13 provides adequate written description to exclude the recited modifications.

The examiner also argued that, even if the disclosure at page 13, lines 25-32, was sufficient to support “a negative limitation requiring the disseminated tumor cells not be modified prior to passing the fluid through the screen,” the disclosure would not support the negative limitation recited in claims 24 and 28. Examiner’s Answer, pages 11-12. In particular, the examiner argued that the disclosure “would not be sufficient to support a claim requiring the disseminated tumor cells not be modified to *any extent* by any of the means now recited in the present claims, such as antibodies.” Examiner’s Answer, page 12. In addition, the examiner argued that “it is a violation of the written description provision not to include in that recitation the further *alternative* proviso that the disseminated tumor cells are not modified ‘by inducing other defined states.’” Examiner’s Answer, page 13.

Appellants argue that the phrase “‘other defined states’ was left out to obviate the possibility of an indefiniteness rejection. In any event, the written description requirement doesn’t require applicant to recite in the claims all of what is at page 13, lines 25-32.” Reply Brief, page 3.

We agree with Appellants that there is no requirement that the claims exclude all of the modifications recited at page 13, lines 25-32. As noted in In re Johnson, “[t]he notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph,

appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.” 558 F.2d at 1019, 194 USPQ at 196 (emphasis added). Thus, we do not agree with the examiner that the failure to exclude modification by “inducing other defined states” causes claims 24 and 28 to lack written description.

We also do not agree that the examiner has properly construed claims 24 and 28. We agree with the examiner that the claim language is somewhat ambiguous. However, when the claims are given their broadest reasonable interpretation consistent with the specification, claims 24 and 28 each require that the tumor cells are not modified – using antibodies, enzymes, lectins, other ligands, other receptors, or crosslinking reagents – by labeling, attaching particles, triggering aggregation, and/or triggering cluster formation and are not modified by fixing.

As properly construed, we do not agree that claims 24 and 28 exclude disseminated tumor cells that are modified with antibodies in any way. Thus, we do not agree with the examiner’s argument that excluding this subject matter causes claims 24 and 28 to lack written description. Instead, because we have construed claims 24 and 28 consistent with the disclosure at page 13, lines 25-32, we agree with Appellants that the examiner has not shown that this disclosure fails to provide support for the negative limitation of claims 24 and 28.

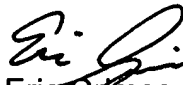
Summary

The examiner has not shown that claims 24 and 28 are not supported by the present specification. We therefore reverse the written description rejection of claims 24 and 28.

REVERSED



Donald E. Adams
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge



Nancy J. Linck
Administrative Patent Judge

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